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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,714	09/26/2003	Thomas P. Castellano	P 304309 304309	1147
7590 09/19/2005			EXAMINER	
Pillsbury Winthrop LLP Intellectual Property Group 725 South Figueroa Street, Suite 2800 Los Angeles, CA 90017-5406			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/672,714

Applicant(s)

CASTELLANO, THOMAS P.

Examiner

Catherine S. Williams

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,7-9,11,13-14,16 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Trautman et al (USPubN 2002/0091357). Trautman discloses an injection apparatus with a housing and a group of about 30-40 lancets and an injection spring to drive the lancets out of the housing upon actuation. The device also includes a push button trigger, a cap, a lancet base, at least two shear pins and four guides that are configured at quarter turns around the base of the housing. The outside of the housing is considered a finger rest. See figures 2,4-7 and paragraphs 0035,0037,0053 and 0056.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 23-24, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman in view of Kramer et al (USPN 5,451,210). Trautman meets the claim limitations

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as described above but fails to include the safety spring. However, Kramer provides a safety spring. See figure 6.

At the time of the invention, it would have been obvious by one skilled in the art to incorporate the safety spring of Kramer into the invention of Trautman. The problem of inadvertant needle sticks is well known in the art and the use of springs at the injection end of device is a well know mechanism for providing retraction of the needle after use to prevent a needle stick. The motivation for incorporating the spring as taught by Kramer into the invention of Trautman would have been in order to enhance the safety of the device to the medical technician.

Claims 15 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman alone or in view of Kramer and in further view of Chiappetta (USPN 5,989,229). Trautman alone or Trautman in view of Kramer meet the claim limitations as described above but fail to teach a soft matrix in the cap. However, Chiappetta discloses such a matrix for enhancing the sterility of the needle prior to use. See figures 3-4.

At the time of the invention, it would have been obvious by one skilled in the art to incorporate the soft matrix of Chiappetta into the invention of Trautman alone or Trautman in view of Kramer to enhance the sterility of the device prior to use.

Claims 10 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman alone or in view of Kramer. Trautman alone or Trautman in view of Kramer meet the claim limitations as described above but fail to teach specifically 36 lancets or one of the claimed

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drugs. However, at the time of the invention it would have been an obvious design choice by one skilled in the art to use 36 lancets or the claimed drugs. Applicant has not disclosed that 36 lancets over another number of lancets or the claimed drug over other drug provides an advantage, is used for a particular purpose or solves a stated problem. Additionally, one would expect the claimed particulars and the prior art device to perform equally well in administering an agent into or through the epidermis.

Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman alone or in view of Kramer in further view of Herrick (USPN 102262). Trautman alone or Trautman in view of Kramer meet the claim limitations as described above but fail to teach a pair of finger rests. However, Herrick teaches such a finger rest. See figures 1-2.

At the time of the invention, it would have been obvious to incorporate the pair of finger rests as taught by Herrick into the invention of Trautman alone or Trautman in view of Kramer. Finger rests are well known in the syringe, lancet, needle art and are commonly used to provide the device with an enhanced grip for actuation of the device.

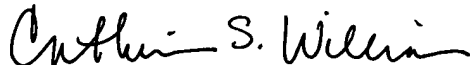
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
September 15, 2005